

Remarks

Claims 61-68 were pending. Claims 61-68 were rejected.

Claims 61, 67 and 68 have been amended to more clearly recite the present invention.

Support for amendments made herein is apparent or is described below. Thus, no new matter is added.

The Abstract

The Examiner noted that an Abstract of the Disclosure was missing. Applicant submits herewith a copy of the Abstract submitted in priority application PCT/EP99/03822.

Rejections under 35 U.S.C. §112(2)

Claim 61 was rejected under 35 U.S.C. §112, second paragraph for indefiniteness in recitation of the term, “matching.” Claim 61 has been amended to no longer recite the term, “matching.” Withdrawal of rejection is respectfully requested.

Claim 68 was rejected under 35 U.S.C. §112, second paragraph for lack of antecedent basis in recitation of the term, “vaccine.” Claim 68 has been amended to correct this clear typographical error and to recite proper antecedent basis. Amendment to claim 68 is meant solely to correct a typographical error and is not meant to exclude vaccines as a member of the more general class of immunogenic compositions. Withdrawal of rejection is respectfully requested.

Claim 61 was rejected as being vague and unclear in reciting “T-cell immune response to a polypeptide having the sequence of SEQ ID NO:2 or SEQ ID NO:4.” In particular, the Examiner alleged that it is not clear what T-cell immune response applicant intends.

Applicant wishes to thank Examiner Baskar for her kindness shown to Applicant’s representative Teresa Bittenbender in the telephonic interview on November 7, 2002. As suggested in that telephonic interview, claim 61 has been amended to recite, “T-cell mediated immune response”. Support for this amendment can be found in the specification on page 34, third paragraph (“These categories of response have been termed TH1-type responses (cell-mediated response)..”). Thus, no new matter is added. Withdrawal of rejection is respectfully

requested.

Rejections under 35 U.S.C. §102(b)

Claims 61-64 and 67-68 were rejected under 35 U.S.C. §102(b) as being anticipated by Bartos et al (J. Infec. Dis, 158; 761-765 (1988). In particular, the Examiner alleged,

Bartos et al discloses an isolated polypeptide, outer membrane protein i.e., OMP from whole cell lysate of 50 strains of *M. Catarrhalis* (page 762, left and figure 1). Polyclonal antibodies were produced by administering (i.e., immunizing) p-antigen to rabbits (page 764, right column first paragraph) indicating surface antigens are immunogenic. Applicant's use of the open-ended term "comprising" in the claims fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on the disclosed isolated polypeptide, IMP from *M. catarrhalis*.

Whole cell lysates from *M. catarrhalis* inherently comprise the amino acid sequence as set forth in the SEQ ID NO:2 or 4 and fragments of SEQ ID NO:2 or 4 See In re Horvitz, 168 F.2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO D. App. 1948). In the absence of evidence to the contrary the disclosed prior art protein and the claimed isolated polypeptide comprising (a) an amino acid sequence matching SEQ ID NO:2 are the same. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated polypeptide comprising SEQ ID NO:2 with the polypeptide of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 U.S.P.Q. 594.

Applicants disagree. A claim is anticipated by a reference only if each and every element of the claim is found, either expressly or inherently, in that reference. *MPEP 2131*. Moreover, the identical invention must be shown in **as complete detail as is contained in the claim**. *Id.* Abiding by these standards, Bartos et al. clearly does not anticipate the invention as claimed in claims 61-68.

Claims 61-68 are directed to immunogenic polypeptides comprising SEQ ID NO:2, SEQ ID NO:4, or at least 15 contiguous amino acids of SEQ ID NO:2 or SEQ ID NO:4 as well as associated immunogenic compositions with pharmaceutically acceptable carriers. Bartos et al. is directed to a comparison of groups of outer membrane proteins between particular strains of *M.*

catarrhalis. Bartos et al does not disclose, either expressly or inherently, the polypeptide sequences claimed in the present claims 61-68. Bartos does not disclose any particular polypeptide sequence, much less that of SEQ ID NOS: 2 or 4. Bartos et al. also does not disclose in as complete detail as is contained in the claim an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ ID NO:2 or SEQ ID NO:4 or immunogenic compositions containing a pharmaceutically acceptable carrier. Thus, abiding by the standards set forth in MPEP 2131, Bartos et al. fails to anticipate claims 61-68.

Claims 61, 63 and 67 were rejected under 35 U.S.C. §102(b) as being anticipated by Blattner et al. 1997 (Accession Number A 64742). In particular, the Examiner alleged that

Claims are directed to an isolated polypeptide comprising a member selected from the group consisting of an (a) an amino acid sequence matching SEQ ID NO:2 (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ ID NO:2, where in the isolated polypeptide induces an antibody or T-cell immune response.

Since “matching” in claim 1 is not clear, the office is interpreting the claim as an isolated polypeptide that matches with SEQ ID NO:2 in any place that can elicit an immune response.

Blattner et al disclose an isolated polypeptide (see sequence alignment marked) comprising an amino acid sequence matching SEQ ID NO:2. The art teaches that the antigen or epitope is roughly 5 amino acids in size (Levinson et al Medical Microbiology & Immunology 1994, page 293) can elicit an immune response and react with an antibody. Therefore, Blattner et al meet the limitations (i.e., an isolated polypeptide comprising an amino acid sequence matching SEQ ID NO:2) of the claims.

Claim 61 has been amended to no longer recite the term, “matching,” thus obviating the Examiner’s rejection. Claim 61 as presently amended (and dependant claims 62-68) is not anticipated by Blattner et al, which discloses a peptide only 5 amino acids in length. Withdrawal of rejection is respectfully requested.

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FEE DEFICIENCY

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Closing Remarks

Entry of the Response and Amendment and allowance of the pending claims are respectfully requested.

Respectfully submitted,



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Detail of Amendments Made To Claims

61. (Amended) An isolated polypeptide comprising a member selected from the group consisting of

- (a) the[an] amino acid sequence of[matching] SEQ ID NO:2 or SEQ ID NO:4; and
- (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ ID NO:2 or SEQ ID NO:4;

wherein the isolated polypeptide, when administered to a subject in a suitable composition which can include an adjuvant, or a suitable carrier coupled to the polypeptide, induces an antibody or T-cell mediated immune response to a polypeptide having the sequence of SEQ ID NO:2 or SEQ ID NO:4. ;

67. (Amended) An immunogenic[immogenic] composition comprising the polypeptide of Claim 61 and a pharmaceutically acceptable carrier.

68. (Amended) The immunogenic composition of Claim 67, wherein said immunogenic composition further comprises[the vaccine comprises] at least one other *Moraxella catarrhalis* antigen.

Claims following entry of amendment mailed January 21, 2003

61. (Amended) An isolated polypeptide comprising a member selected from the group consisting of
- (a) the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4; and
 - (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 amino acids that matches an aligned contiguous segment of SEQ ID NO:2 or SEQ ID NO:4;

wherein the isolated polypeptide, when administered to a subject in a suitable composition which can include an adjuvant, or a suitable carrier coupled to the polypeptide, induces an antibody or T-cell mediated immune response to a polypeptide having the sequence of SEQ ID NO:2 or SEQ ID NO:4.

62. The isolated polypeptide of claim 61, wherein the polypeptide is according to (a).
63. The isolated polypeptide of claim 61, wherein the polypeptide is according to (b).
64. The isolated polypeptide of claim 61, wherein the immunogenic fragment of (b) comprises at least 20 amino acids.
65. The isolated polypeptide of claim 61, wherein the isolated polypeptide consists of SEQ ID NO:2 or SEQ ID NO:4.
66. A fusion protein comprising the isolated polypeptide of Claim 61.
67. (Amended) An immunogenic composition comprising the polypeptide of Claim 61 and a pharmaceutically acceptable carrier.
68. (Amended) The immunogenic composition of Claim 67, wherein said immunogenic composition further comprises at least one other *Moraxella catarrhalis* antigen.